Oscar Clinical Guideline: sodium oxybate (Xyrem) (PG009, Ver. 6)

sodium oxybate (Xyrem)

Summary

Sodium oxybate, also known by the brand name Xyrem, is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. As the sodium salt of gamma hydroxybutyric acid (GHB), this drug has a unique capability to decrease cataplexy episodes and alleviate symptoms of EDS.

Narcolepsy is a chronic condition that affects the central nervous system, resulting in irresistible daytime sleepiness, intermittent night sleep, and in numerous instances, cataplexy—an abrupt loss of muscle control incited by strong emotions. Other symptoms related to the abnormal regulation of REM sleep can include sleep paralysis and hallucinations during sleep onset or awakening.

Clinical trials have demonstrated sodium oxybate's potency in reducing cataplexy episodes and managing EDS in patients with narcolepsy. Notably, a near 70% median decrease in weekly cataplexy incidents has been documented in adult patients given a 9 gram nightly dosage. However, due to

Sodium oxybate's euphoric effects, there is a risk for misuse. It has a past history of recreational use as a "party drug," leading to its classification as a Schedule III controlled substance. To safeguard against misuse while ensuring that patients who require the medication can access it, stringent distribution guidelines have been implemented. These regulations include using a central pharmacy, having physicians registered with the pharmacy, verifying physician eligibility, and requiring patients to register and familiarize themselves with educational materials about the drug.

Definitions

"Cataplexy" is sudden muscle weakness that is uncontrollable and often triggered by a positive emotion such as laughter, fear, stress, anger or excitement.

"Hypocretin-1" is a natural chemical in the brain that helps regulate wakefulness.

"Multiple sleep latency test (MSLT)" is a sleep study used to measure the time it takes to fall asleep during the daytime.

"Polysomnography (PSG)" is a sleep study used to diagnose sleep disorders by measuring certain components such as brain activity, oxygen levels, heart rate, breathing, eye movements, and leg movements.

"Sleep latency" is the amount of time it takes to fall asleep.

"Sleep-onset rapid eye movement period (SOREMP)" is achieving rapid eye movement (REM) sleep within 15 minutes of falling asleep.

Medical Necessity Criteria for Initial Authorization

The Plan considers **sodium oxybate (Xyrem)** medically necessary when the ALL the following criteria are met for the applicable indication listed below:

For the treatment of narcolepsy type 1

1. The requested medication is prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist; ***AND***
2. The member is 7 years of age or older; ***AND***
3. The member has a diagnosis of narcolepsy (type 1) per International Classification of Sleep Disorders criteria, defined as meeting **ALL** of the following criteria:

a. Daily instances of excessive daytime sleepiness lasting for a minimum of three months; ***and***
b. Presence of cataplexy; ***and***
c. At least **ONE** of the following:
    i. Mean sleep latency of 8 minutes or less and two or more sleep-onset rapid eye movement periods (SOREMPs) on a multiple sleep latency test (MSLT). A SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnography (PSG) can substitute one of the SOREMPs on the MSLT***; or***
    ii. A cerebrospinal fluid (CSF) hypocretin-1 concentration, measured by immunoreactivity, that is either ≤110 pg/mL or less than a third of mean values obtained in healthy individuals using the same standardized assay; ***and***
d. The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal; ***AND***

4. The member is unable to use, or has adequately tried and failed at least **ONE** (1) of the following medications for at least 30 days duration:
    a. amphetamine-dextroamphetamine; ***or***
    b. dextroamphetamine; ***or***
    c. methylphenidate; ***or***
    d. armodafinil; ***or***
    e. modafinil; ***AND***
5. The member is unable to use, or has adequately tried and failed at least **THREE** (3) total medications for the treatment of cataplexy for at least 30 days duration each:
    a. SSRIs (such as fluoxetine); ***and/or***
    b. SNRIs (such as venlafaxine); ***and/or***
    c. Tricyclic Antidepressants (such as clomipramine); ***AND***
6. The member must not be using a sedative hypnotic medication in combination with sodium oxybate (Xyrem); ***AND***
7. Chart documentation and supporting lab work are provided for review to substantiate the above-listed requirements.

For the treatment of narcolepsy type 2

1. The requested medication is prescribed by or in consultation with a neurologist, psychiatrist, or sleep specialist; ***AND***
2. The member is 7 years of age or older; ***AND***
3. The member has a diagnosis of narcolepsy (type 2) per International Classification of Sleep Disorders criteria, defined as meeting **ALL** of the following criteria:
    a. Daily periods of excessive daytime sleepiness lasting for a minimum of three months; ***and***
    b. A mean sleep latency of 8 minutes or less and two or more sleep onset rapid eye movement periods (SOREMPs) detected on a multi-sleep latency test (MSLT). A SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnography (PSG) can replace one of the SOREMPs on the MSLT; ***and***
    c. Either CSF hypocretin concentration has not been measured or CSF hypocretin concentration, measured by immunoreactivity, is either >110 pg/mL or more than a third of mean values obtained in healthy individuals using the same standardized assay; ***and***
    d. The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal; ***AND***
4. The member is unable to use, or has adequately tried and failed at least **THREE** (3) total medications for at least 30 days duration each:
    a. amphetamine-dextroamphetamine; ***and/or***
    b. dextroamphetamine; ***and/or***
    c. methylphenidate; ***and/or***
    d. armodafinil; ***and/or***
    e. modafinil; ***AND***
5. If Sunosi (solriamfetol) is a Formulary alternative, the member is unable to use, or has adequately tried and failed Sunosi (solriamfetol) at the maximum tolerated dose for at least a 30 day duration; ***AND***
6. The member must not be using a sedative hypnotic medication in combination with sodium oxybate (Xyrem); ***AND***
7. Chart documentation and supporting lab work are provided for review to substantiate the above-listed requirements.

If the above prior authorization criteria are met, sodium oxybate (Xyrem) will be approved for 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization of 12 months will be provided if the member still meets the applicable initial criteria, and there is documented clinical response in chart notes meeting the following criteria:

1. For Narcolepsy Type 1
    a. A reduction in the frequency of cataplectic episodes; ***or***
    b. A reduction in the symptoms of excessive daytime sleepiness; ***OR***
2. For Narcolepsy Type 2
    a. A reduction in the symptoms of excessive daytime sleepiness

Experimental or Investigational / Not Medically Necessary

sodium oxybate (Xyrem) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Sodium oxybate (Xyrem) has been studied for various indications beyond its approved uses. However, the current evidence is limited and inconclusive for these non-supported indications:

- Alcohol Dependence/Alcohol Use Disorders (AUD)
- Alcohol Withdrawal Syndrome
- Alternating Hemiplegia of Childhood
- Anxiety, Post Traumatic/Post Traumatic Stress Disorder (PTSD)
- Binge Eating Disorder (BED)
- Chronic Fatigue Syndrome/Myalgic Encephalitis (CFS/ME)
- Cluster Headache
- Essential Tremor
- Fibromyalgia
- Hypersomnia
- Idiopathic Hypersomnia
- Insomnia Related to Schizophrenia/Schizophrenia
- Laryngeal Tremor/Spasmodic Dysphonia
- Obstructive Sleep Apnea (OSA)
- Parkinson's Disease (PD)/Rapid Eye Movement Sleep Behavior Disorder
- Sedative Abuse Prevention
- Sleep Initiation and Maintenance Disorders
- Traumatic Brain Injury (TBI)

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